

### **REMARKS**

Claims 1-26 and 44-47 are pending in this application. Claims 27-43 have been previously canceled without prejudice or disclaimer of the subject matter contained therein.

Claim 1 has been amended above, and claims 48-57 are newly added.

Support for the above amendments appears throughout the originally filed specification, claims, and drawings. Specifically, the amendments to claim 1 are supported on page 2, lines 24-25, page 5, line 20, page 5, line 22 thru page 6, line 15, and page 6, line 27 thru page 7, line 6 of the originally filed specification. Further, Figure 6 shows the direct and tight sliding contact between the flexible container and inner walls of the cooling plates.

Regarding newly added claim 48, support is provided on page 3, lines 13-17 of the originally filed specification.

Regarding newly added claim 49, support is provided on page 5, line 8 of the originally filed specification.

Regarding newly added claims 50-52, support is provided on page 7, lines 2-6 of the originally filed specification.

Regarding newly added claim 53, support is provided on page 5, lines 24-26 of the originally filed specification.

Regarding newly added claim 54, support is provided on page 3, lines 13-15 of the originally filed specification.

Regarding newly added claims 55-57, support is provided on page 5, lines 22-28 of the originally filed specification.

Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled or the original claim scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicants request reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

***I. Claims 1-26, 44, 45, and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Arav (US 5,873,254) and Polk (US 3,074,247) as set forth on page 2 of the Official Action.***

The Examiner asserts that “[It] would have been obvious to a person of ordinary skill in the art to allow for the passage inner width to conform to a container outer width in order to increase the heat transfer rate from the cryogenic fluid to the sample container to achieve an efficient and fast method of freezing a biological sample.”

The Examiner further asserts that “[It] would have been obvious to a person of ordinary skill in the art at the time of invention to modify Arav with the teachings of Polk to include an inner width that conforms to an outer width of the container and cooling along the cooling axis by conduction between the inner surfaces of the cooling plates and the container that when combined with Arav, cooling the sample would be accomplished by conduction from direct contact between the container and the inner surfaces of the plates in order to increase the amount of heat transferred from the container to the cryogenic fluid. This results in a faster cooling rate due to the direct

contact of the sample container and the place containing the cryogenic fluid.” These rejections are respectfully traversed.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

**Arav** discloses a device for multigradient directional cooling and warming of biological samples, including three blocks 12, 14, and 16, as shown in Fig. 1A. “A tunnel 36, preferably of rectangular cross section, runs through blocks 12, 14, and 16. Tunnel 36 defines a track along which a sled 40 is moved. Sled 40 preferably is made of a thermally conductive material, preferably copper, and bears one or more straws 38 that contain biological samples to be frozen or thawed. Straws 38 typically are hollow tubes of circular or rectangular cross section, about 14 to 30 centimeters long. Sled 40

is moved through tunnel 36 by a piston 42 to which is attached a helically threaded rod 44.” See column 3, line 65 thru column 4, line 8.

As shown in the embodiment of Fig. 1A, the width of the straw 38 is a fraction of the width of the tunnel 36 or track. Further, the straw 38 is **not** in contact with the inner walls of the tunnel 36 due space located above and the sled 40 positioned below the straw 38.

As shown in the embodiment of Fig. 2, the width of the straw 38 again is a fraction of the width of the tunnel 36. Further, the straw 38 is **not** in contact with the inner walls of the tunnel 36 due to the pairs of rollers 120 gripping straw 38 frictionally and moving the straw 38 downwards through tunnel 36. The pairs of rollers 120 space apart the straw 38 from the inner walls of the tunnel 36. See column 5, lines 2-8.

**Polk** discloses an apparatus for use in freezing packaged products, including “a pair of hollow metal plates designated 11 which can be mounted in any suitable manner for limited lateral movement relative to each other in a direction toward and away from each other.” See column 1, lines 54-57.

Polk further discloses an elevator 15 for raising and lowering rows of packages P, as shown in Fig. 1

The plates 11 are separated apart (Fig. 1) to introduce a row of packages P into the widened space 16 via elevator 15. The plates 11 are closed together (Figs. 3, 5, and 6), after a row of packages is positioned in the space 16. It is noted that the plates 11 are moved apart when using elevator 15 to move one or more rows of packages P into or out of the space 16. The plates 11 are moved together only after the one or more rows of packages P are positioned stationary or static within the space 16 to then

apply cooling processing. Thus, the rows of packages P are not moved (e.g. in sliding contact with inner walls of plates 11) when the plates 16 are moved together. The plates 11 lock the one or more rows of packages P into a stationary position, and preclude movement thereafter, until the plates 16 are later separate apart for loading or unloading rows of packages P. ***Thus, according to Polk, the packages, once in place, remain stationary or static at their position.***

In attempting to applying the teaching of Polk to the first embodiment shown in Fig. 1A of Arav (i.e. reduce width of tunnel 36 in device of Arav to the combined width of straw 38 and sled 40), it is noted that the width of the piston 42 is shown slightly wider than the combined width of straw 38 and sled 40 making the proposed modified device inoperable due to piston 42 being captured by squeezing between the side walls of the tunnel 36 preventing it movement or operation thereof.

Further, it is noted that in such modification, the one side wall of the straw 38 would still not be in contact with the upper side wall (Fig. 1A) of the tunnel 36 in the device of Arav. In addition, the lower side wall of the straw 38 is in contact with the upper surface of the sled 40, and ***not*** in contact with the lower side wall of the tunnel 36. Thus, this modification is clearly ***not*** suggested.

In attempting to apply the teaching of Polk to the second embodiment shown in Fig. 2 of Arav (i.e. reduce width of tunnel 36 in device of Arav to the width of straw 38), it is noted that there would be no room for the pairs of rollers 120 to exist, let alone rotate and operate to move the straw 28 making the proposed modified device inoperable. Thus, this modification is also clearly ***not*** suggested.

Again, Polk by itself teaches no sliding contact of the rows of packages P with the inner walls of the plates 11, and requires separation of the plates 11 prior to moving the one or more rows of packaging P into a stationary position in the space 16, or from a stationary position within the space 16.

It is also noted that Arav discloses that the “straws are special transparent (typically glass) straws of rectangular cross section” (See column 4, lines 48-49), which language does **not** suggest the “flexible container” or use of the “flexible container” according to the claimed subject matter wherein the cooling plates are configured to maintain direct and tight sliding contact with the flexible container as it passes through the passage (e.g. non-flexible rigid straw 36 of Arav would tend to cause jamming when moving through tunnel 36, if tunnel width is reduced to width of straw 36).

Arav and Polk both do **not** disclose any sliding contact between the cooling plates and flexible container, let alone “wherein the cooling plates are configured to maintain direct and tight sliding contact with the flexible container as it passes through the passage” according to the claimed subject matter.

Thus, nothing is Arav and Polk, taken alone or in combination, render the subject matter of the of claims 1-26, 44, 45, and 47 obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**II. Claim 46 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Arav and Polk as applied to claim 1 above, and further in view of Eck et al. (DE Publication No. 10056181 C1).**

The Examiner asserts that “[It] would have been obvious to a person of ordinary skill in the art at the time of invention to modify the combined teachings of Arav and Polk with the teachings of Eck to include a blood bag for the container in order to increase the amount of biological material that can be cooled and stored at one time. The increased size of the bag allows more material to fit within it. Further, the efficiency of the system is increased as the time needed to freeze a given amount of biological sample is decreased due to the increased capacity when using the blood bag.” This rejection is respectfully traversed.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

**Arav** and **Polk** are discussed in detail above in the response set forth in paragraph I.

**Eck et al.** is cited by the Examiner as disclosing cryogenic storage of blood samples that uses a blood bag.

Eck et al., like Arav and Polk, do **not** disclose any sliding contact between cooling plates and a flexible container, let alone “wherein the cooling plates are configured to maintain direct and tight sliding contact with the flexible container as it passes through the passage” according to the claimed subject matter.

Thus, nothing is Arav, Polk, and Eck et al., taken alone or in combination, render the subject matter of the of claim 46 obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.



## **CONCLUSION**

Applicants believe that a full and complete response has been made to the pending Office Action and respectfully submit that all of the stated grounds for rejection have been overcome or rendered moot. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative at the number below to expedite prosecution.

If an extension of time is necessary to prevent abandonment of this application and is not filed herewith, then such extension of time is hereby petitioned for under 37 C.F.R. §1.136(a). Any fees required for further extensions of time and any fees for the net addition of claims are hereby authorized to be charged to our Deposit Account No. 14-0112. Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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